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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/632,145

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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT

PAPER NUMBER

3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/16/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/632,145

Applicant(s)

SEGNER ET AL.

Examiner

Jeffrey G. Hoekstra

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/20/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-19, 22-35, 37-40 and 43-49 is/are pending in the application.
- 4a) Of the above claim(s) 3-6, 10, 11, 16, 22, 23, 26-29, 31, 32, 37, 43-47 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 7-9, 12-14, 17-19, 24, 25, 30, 33-35, 38-40 and 48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 11/20/2006, amended claim(s) 1,7,8,11,14,17,18,24,32,35,38,39,45,46,48, and 49, withdrawn claim(s) 3-6,10,11,16,22,23,26-29,31,32,37,43-47, and 49, and canceled claim(s) 15,20,21,36,41, and 42 is/are acknowledged. The current rejections of the claim(s) 1-14,16-19,22-35,37-40, and 43-49 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Information Disclosure Statement

2. The information disclosure statement(s) (IDS) submitted on 09/21/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 24, 30, 33-35, 38-40, and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Avellanet et al (US 6,019,736). Avellanet et al discloses a guidewire (60, 70, 85, 100) as best seen in Figures 10-12, comprising:

- (a) an elongate, flexible core (61, 71, 86) having a distal taper (63, 73, 87) and extending to the distal end of the guidewire as seen in Figures 10 and 11;
- (b) a single coil (89, 116) disposed on at least a distal portion of said core (column 8 lines 39-61), said coil comprising 3 to 24 wire strands (column 4 lines 12-19 and column 8 line 39 – column 9 line 10) helically wrapped parallel to one another forming a stranded tubular structure wherein the angle between the wire strands and the longitudinal axis of the guidewire is capable of being between 10 and 45 degrees; and
- (c) a polymer tie layer 120 disposed on at least a portion of the wire strands wherein said tie layer provides the only attachment between the wire strands and the core (column 9 lines 4-39).

5. For claims 30, 33-35, and 38-40, Avellanet et al discloses a guidewire (60, 70, 85, 100) as best seen in Figures 10-12, comprising: a guidewire with an outer diameter of about 0.33 mm or 0.013 inches (column 8 lines 39-61) and a length range of 125 to 300 cm (column 1 lines 23-52), a coil with an outer diameter of about 0.25 mm or 0.0098 inches (column 3 lines 47-52) and a length of about 25 cm (column 8 lines 39-61), and a tapered core region capable of being between 5 to 80 cm.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1, 2, 7-9, 12-14, 17-19, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Avellanet et al in view of Palermo et al (US 5,749,837).

9. For claims 1, 2, 8, and 25, Avellanet et al discloses the claimed invention as discussed above except for explicitly disclosing: (a) a lubricious polymer layer disposed on a polymeric tie layer disposed along the entire length of the guidewire's distal end and (b) attaching the coil comprised of a plurality of wire strands to the core by adhesive or solder. Palermo et al teaches a guidewire (200), comprising: an elongated flexible core (202), a distally disposed coil (112) fixedly attached to said core with a polymer adhesive (136) and solder (128), a polymeric tie layer (204) disposed along the entire

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distal length of said guidewire, and a lubricious polymer layer or coating (206) disposed on said polymeric tie layer (columns 10-15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the guidewire as taught by Avellanet et al, with the lubricious polymer layer and fixed attachments as taught by Palermo et al for the purpose of configuring the mechanical properties of a guidewire for increased patient safety whilst traversing tortuous vasculature with a guidewire during advanced intravascular surgical procedures.

10. For claim 7 as aforementioned, Avellanet et al discloses a guidewire (60, 70, 85, 100) as best seen in Figures 10-12, comprising: a polymer tie layer 120 disposed on at least a portion of the wire strands wherein said tie layer provides the only attachment between the wire strands and the core (column 9 lines 4-39).

11. For claims 12-14 and 17-19 as aforementioned, Avellanet et al discloses a guidewire (60, 70, 85, 100) as best seen in Figures 10-12, comprising: a guidewire with an outer diameter of about 0.33 mm or 0.013 inches (column 8 lines 39-61) and a length range of 125 to 300 cm (column 1 lines 23-52), a coil with an outer diameter of about 0.25 mm or 0.0098 inches (column 3 lines 47-52) and a length of about 25 cm (column 8 lines 39-61), and a tapered core region capable of being between 5 to 80 cm

Response to Arguments

12. Applicant's arguments filed 11/20/2006 have been fully considered but they are not persuasive. Applicant argues [1] the 102(b) and [2] the 103(a) rejections of the claims under Avellanet et al, specifically arguing for both that Avellanet et al does not

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disclose, teach, or suggest the claimed guidewire having a coil comprising 3 to 24 wire strands, each of the 3 to 24 wire strands being formed in a single helix and wrapped helically parallel to one another to thereby form a single coil, wherein the single coil has a longitudinal axis and an interior, and wherein the angle between the wire strands and the axis is from 10 to 45 degrees. The Examiner disagrees, maintains the rejections of the claims, and notes the following:

13. Avellanet et al discloses the claimed guidewire (elements 85 and 100) having a coil (elements 89 and 116) comprising 3 to 24 wire strands (the positively recited multifilament drawn round wire "MFDR" positively recited in column 8 lines 48-51 and detailed in at least column 4 lines 12-18 and column 5 line 62 – column 6 line 29), each of the 3 to 24 wire strands being formed in a single helix and wrapped helically parallel to one another to thereby form a single coil (as best seen in Figures 10-11), wherein the single coil has a longitudinal axis (along the length of the guidewire) and an interior, and wherein the angle between the wire strands and the longitudinal axis is capable of being between 10 to 45 degrees. Moreover, Applicant's disclosure and Avellant et al are both concerned with configuring the distal arrangement of a guidewire to control distal flexibility and torque transmission along the guidewire's length.

14. In response to applicant's arguments [2] against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

15. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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